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39607 7590 07/17/2008 PETER K HAHN LUCE, FORWARD, HAMILTON, SCRIPPS, LLP. 600 WEST BROADWAY SUITE 2600 SAN DIEGO, CA 92101				
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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/912,576
Filing Date: July 24, 2001
Appellant(s): ALLEN ET AL.

Peter K. Hahn
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 14 May 2008 appealing from the Office
action mailed 8 January 2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct. No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

Art Unit: 1700

(7) Claims Appendix

A substantially correct copy of appealed claim 35 appears on page 12 of the Appendix to the appellant's brief. The minor errors are as follows: The claim should end with a period (".").

(8) Evidence Relied Upon

5,590,602	PECK et al.	1-1997
6,030,554	ICHIHARA	2-2000
JP 2000-312708	DOI	11-2000

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1700

Claims 1, 3, 4, 6, 7, 9-15, 17-35, and 37-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doi (JP 2000-312708, see translation) in view of Ichihara (US 6,030,554).

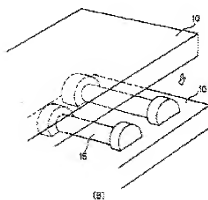
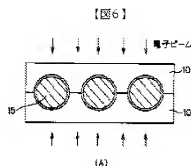
Doi teaches a method and apparatus for electron beam sterilization of articles (dialyzers) **15**. Doi discloses that the articles **15** absorb radiation at different positions in accordance with irregularities in the characteristics of the articles at the different

positions. See translation, paragraphs [0004]-[0006].

The articles are provided in a predetermined configuration (side-by-side) within a "container" (lower half of **10** in Figure 6A). To provide a uniformity of dosage, a regulator (upper half **10**) is provided to absorb the radiation passing from a source **20** (Figure 5) wherein the regulator **10** is fabricated of a shape and material such that it absorbs radiation passing from the source to the articles at the different positions in the container in accordance with the irregularities in the characteristic of the article at the different positions to maintain the radiation dose at the different positions in the article within particular minimum and maximum limits. See

paragraphs [0007]-[0008]; [00020]-[0022]. The "container" may be moved past the source on a conveyor along with the regulator. See paragraph [0026]. The conveyor moves transverse and substantially perpendicular to the radiation. See Figures 5 and

A



6A. Doi further teaches that the regulator **10** may be fabricated of a material having a "consistency almost equivalent to an irradiated object" and has a shape/geometry complementary to the object. A suggested material is aluminum. See paragraphs [0021] and [0027]; Figure 6A.

While Doi teaches two regulators **10** (wherein the bottom regulator also functions as a container for the articles) in Figures 6A and 6B, Doi is silent with respect to a separate container for the articles, which container holds the articles and wherein the two regulators are disposed *external* to the container. Indeed, the regulators of Doi merely hold the articles during radiation and do not maintain sterility of the articles after sterilization. However, Ichihara discloses that "terminal sterilization", the sterilization of an article within its final packaging, is known in the art in the field of electron beam sterilization. See Abstract. In the invention of Ichihara, an article is placed within a "sealed" (i.e. closed) container which permits transmission of electron beam radiation, but prevents entry of microorganisms into the container. See col.2, lines 31-39. Therefore, once the article is sterilized, it will not be recontaminated by subsequent packaging and/or handling. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to package the articles (dialyzers) of Doi prior to sterilization, in order to prevent subsequent recontamination of the dialyzers. In doing so, the regulator **10** would have been placed *external* to the packaging.

Doi teaches conveying articles **15** past a radiation source **20** in a direction substantially perpendicular to the direction of radiation and the use of a fixture **10** designed to provide a uniform level of absorbed radiation throughout the article. See

paragraph [0026]; Figures 6A,B. Therefore, although Doi does not specifically disclose that the conveyor moves the articles at a substantially constant speed, it would have been obvious to one of ordinary skill in the art to do so in order to provide a uniform level of absorbed radiation throughout the length of the article. The concept of uniformity of absorbed radiation is clearly taught by Doi.

Claims 16 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doi and Ichihara as applied to claims 15 and 32 above, and further in view of Peck et al. (US 5,590,602).

Doi is silent with respect to spacing adjacent containers and fixtures by a particular distance when being moved past the radiation source. Peck et al. teaches a method and apparatus for electron beam sterilization of articles wherein the articles are conveyed within containers that are spaced from adjacent containers to achieve "optimum article throughput efficiency" (col.5, lines 19-30). Peck et al. further discloses that in order to "most efficiently utilize the energy of the radiation beam emitted by the radiation source **10**, the spacing between the article carriers **17** as they are transported by the process conveyor **14** past the radiation source **10** must be as small as practically possible." See col.5, lines 61-65. Therefore, it would have been obvious to space adjacent containers and fixtures being conveyed by the conveyor of Doi by a particular distance within particular limits so as to "most efficiently utilize the energy of the radiation beam emitted by the radiation source", as taught by Peck et al..

As to claim 36 specifically, Doi teaches conveying articles **15** past a radiation source **20** in a direction substantially perpendicular to the direction of radiation and the use of a fixture **10** designed to provide a uniform level of absorbed radiation throughout the article. See paragraph [0026]; Figures 6A,B. Therefore, although Doi does not specifically disclose that the conveyor moves the articles at a substantially constant speed, it would have been obvious to one of ordinary skill in the art to do so in order to provide a uniform level of absorbed radiation throughout the length of the article. The concept of uniformity of absorbed radiation is clearly taught by Doi.

(10) Response to Argument

(A) Whether claims 1, 3, 4, 6, 7, 9-15, 17-35, and 37-52 are rendered obvious by a combination of Doi and Ichihara.

On page 11 of the Brief, Appellant submits that "Doi discloses that articles are stopped in position prior to being irradiated. Specifically, Doi discloses that when a dialyzer is correctly positioned with respect to the impression of the dosage regulator, the electron beam tube discharges an electron beam. (Doi at ¶ 0023) Furthermore, Doi discloses that by attaching the dosage regulator directly to the articles, the tolerance for positioning accuracy is reduced (Doi at ¶ 0026), but never discloses that the articles are carried past the radiation source at a constant speed."

In Response, the Examiner would note that Applicant is describing only a single embodiment of Doi, specifically that shown in Figures 4 and 5 and described in paragraphs [0020]-[0025]. For purposes of the rejection, the Examiner set forth the embodiment illustrated by Figure 6 and described in paragraphs [0026]-[0028]. In this embodiment, the dialyzers are placed inside the dose regulator **10** and conveyed past the electron beam irradiator. The articles are NOT disclosed to be stopped in position prior to being irradiated. In fact, Doi teaches that the "irradiation body thus obtained is conveyed by means such as a conveyor belt, and sterilized en route by electron beam irradiation from above and below." Moreover, Doi discloses in paragraph [0007] that the dose regulator "is constituted so that the absorption rate...is constant at all points on the subject of irradiation along a direction perpendicular to the direction of irradiation of the electron beam...." It would have been readily apparent to one of ordinary skill in the art that if the conveyor belt fails to move at a constant speed, the amount of radiation received along the length of the article is not going to be constant, effectively destroying the purpose of the dose regulator.

On page 14 of the Brief, Appellant argues that neither Doi nor Ichihara disclose a separate container for multiple articles and a radiation regulator disposed external to the container. In response, the Examiner notes that if either Doi or Ichihara did disclose a radiation regulator coupled to an external surface of a closed container, they would be anticipatory references. However, anticipation is not required to reject the claims. Doi teaches a radiation absorbing fixture (top half of **10**) coupled to the external surface of articles placed within a container (bottom half of **10**). Ichihara discloses the radiation

sterilization of a sealed container – i.e. *terminal sterilization*. Thus, Ichihara provides the motivation to enclose the articles of Doi within a closed container prior to sterilization. Specifically, by packaging the dialyzers of Doi within a sealed container prior to enclosing them within the dose regulator **10**, one prevents recontamination of the sterilized dialyzers by subsequent packaging and handling steps. This concept is known in the art as '*terminal sterilization*'. The combination of Doi with Ichihara results in placing the removable fixture of Doi on the external surface of the sealed container suggested by Ichihara.

Continuing on page 14 of the Brief, Appellant contends that "there is not disclosure in either reference of a closed container that houses a plurality of articles in a predetermined configuration." The Examiner respectfully disagrees. Doi clearly teaches placing the dialyzers in a predetermined configuration (side-by-side) within the dose regulator **10**. They must be placed in a particular configuration in order to receive proper dose absorption by the dose regulator. When combining Doi with Ichihara, one would have maintained the same configuration of articles within the sealed container such that the dose regulator would still be effective in absorbing radiation.

On page 15 of the Brief, Appellant states that "the present invention specifically teaches the advantages of disposing a fixture external of a closed container." However, the combination of Doi with Ichihara also teaches the advantages of terminal sterilization, which would require disposing the fixture external to a closed container.

On page 16 of the Brief, Appellant argues that "Ichihara discloses that the electron beam is activated after the dialyzers are positioned correctly with respect to the dosage regulator that is coupled to the radiation source. As a result, it is clear that the dialyzers are stopped relative to the radiation source prior to irradiation." The Examiner assumes Appellant meant to refer to Doi. Regardless, Appellant is describing the embodiment of Figures 4 and 5. In the description of Figure 6, paragraph [0026], Doi discloses that in contrast to the embodiment in Figures 4 and 5, the dose regulator and dialyzer together are conveyed by a conveyor belt and "sterilized en route by electron beam irradiation from above and below." Thus, clearly the dialyzer is NOT stopped prior to irradiation.

(B) Whether claims 16 and 36 are rendered obvious by a combination of Doi, Ichihara and Peck.

While Applicant remarks that Peck does not disclose fixtures for regulating irradiation of articles, the Examiner respectfully notes that Peck is not required to teach such as Peck is combined with Doi which does teach fixtures for regulating irradiation of articles. In fact, Peck was relied upon only for a teaching that it was known in the art at the time of the invention to convey articles within containers that are spaced from adjacent containers to achieve "optimum article throughput efficiency" (col.5, lines 19-30) in an irradiation method and apparatus.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Elizabeth L McKane/

Primary Examiner, Art Unit 1797

Conferees:

/Gladys JP Corcoran/
Supervisory Patent Examiner, Art Unit 1797

/Jennifer Michener/

QAS TC1700

